

Claims:

We claim

~~Subj P~~ 1. Amino acid particles in which a sample of the particles has a bulk density not more than  $0.1 \text{ gcm}^{-3}$ .

5 2. Amino acid particles according to claim 1, in which a sample of the particles has a bulk density not more than  $0.05 \text{ gcm}^{-3}$ .

3. Amino acid particles having a mass median aerodynamic diameter (MMAD) not more than  $5\mu\text{m}$ .

10 4. Amino acid particles being in the form of flakes having a thickness of not more than  $0.5\mu\text{m}$ .

5. Amino acid particles according to claim 4 in which the flakes have a thickness of not more than 100nm.

6. Amino acid particles according to any preceding claim, in which the amino acid is leucine.

15 7. A powder for use in a dry powder inhaler, the powder including active material and amino acid particles according to any of claims 1 to 6

20 8. A powder according to claim 7, in which the powder includes not more than 20% by weight of amino acid based on the weight of the powder.

9. A powder according to claim 8, in which the powder includes not more than 10% by weight of amino acid based on the weight of the powder.

25 10. A powder according to claim 7 or claim 8, the powder further including particles of a diluent.

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11. A powder according to claim 10, in which the diluent includes a crystalline sugar.

Suzy  
A3  
5  
12. A powder according to claim 10 or claim 11, in which the diluent has a particle size such that at least 90% by weight of the diluent particles have a particle size not more than 10 $\mu\text{m}$ .

13. A powder according to claim 10 or claim 11, in which the diluent has a particle size such that at least 90% by weight of the diluent particles have a particles size not 10 less than 50 $\mu\text{m}$ .

14. A powder according to claim 10 or claim 11, in which the diluent has a fine particle portion having a particle size such that at least 90% by weight of the particle of the fine particle portion have a particle size not more than 10 $\mu\text{m}$   
15 and a coarse particle portion having a particle size such that at least 90% by weight of the particles of the coarse particle portion have a particle size not less than 50 $\mu\text{m}$ .

15. A powder according to claim 14, in which the fine particle portion and coarse particle portion comprise the 20 same material.

Suzy  
A4  
16. A powder according to any of claims 14 or 15, in which the powder includes not more than 5% by weight of the fine particle portion based on the weight of the powder.

17. A powder according to any of claims 14 to 16, in which the powder includes not more than 95% by weight of the coarse particle portion based on the weight of the powder.

18. A dry powder inhaler, the inhaler containing powder according to any of claims 7 to 17.

19. A method of preparing particles of amino acid as claimed in any of claims 1 to 6, the method including the step of forming solid amino acid particles from a vapour or from a solvent, the method being such that the particles are formed while being suspended in a gas flow.

20. A method of preparing particles of amino acid as claimed in any of claims 1 to 6, the method including the step of condensing amino acid vapour to form solid amino acid particles.

15 21. A method according to claim 19 or claim 20, in which particles of amino acid are formed by aerosol condensation.

22. A method according to claim 20 or claim 21, in which the method includes the steps of

- 20 a) heating the amino acid so that the amino acid forms a vapour;
- b) mixing the amino acid vapour with cool air to form a cloud of condensed amino acid particles; and
- c) collecting the condensed particles.

23. ~~A method according to any of claims 20 to 22, the method including the step of heating the amino acid particles to a temperature of at least 150°C at ambient pressure.~~

24. A method of producing particles of amino acid, in which droplets of amino acid in a solvent are dried in a spray drying step to form solid particles of amino acid, the method being such that at least some of the amino acid sublimes 5 during the spray drying.

25. A method according to claim 19, in which the method includes the step of spray drying to form solid particles of amino acid.

26. A method according to claim 25, in which the material to be dried comprises amino acid in solution.

27. A method according to claim 24 or claim 26, in which material to be dried comprises amino acid in aqueous solution.

28. A method according to any of claims 24 to 27 in which 15 the droplets dried have a mean size of not more than 10 $\mu\text{m}$ .

29. A method according to any of claims 19 to 28, in which the method is such that the MMAD of the solid amino acid particles produced is not more than 10 $\mu\text{m}$ .

30. A method according to claim 24, the method being such 20 that the amino acid particles produced are amino acid particles according to any of claims 1 to 6.

31. Particles of amino acid obtainable by a method according to any of claims 19 to 29.

32. A method of making a powder according to any of claims 7 25 to 17, the method including the steps of mixing amino acid

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according to any of claims 1 to 6 or claim 31 with active material.

AS  
LOM  
33. A method of making a powder according to any of claims 10 to 17, the method including the step of mixing amino acid 5 according to any of claims 1 to 6 or claim 31 with active material followed by the step of mixing the amino acid and active material with a diluent.

34. Use of particles of amino acid according to any of claims 1 to 6 or claim 31 in a powder to improve the flow 10 properties of the powder.

35. Use of particles of amino acid according to any of claims 1 to 6 or claim 31 in a powder for use in a dry powder inhaler.

36. Particles of amino acid being substantially as herein 15 described.

37. A method of producing particles of amino acid, the method being substantially as herein described.

38. A powder for inhalation, the powder being substantially as herein described.